AMENDMENT

This is in response to the Final Office Action dated December 20, 2004 rejecting claims 1-4 and 6-36. Independent claims 1, 18 and 19 are amended herein. Claims 1-4 and 6-36 remain pending.

Claim Rejections under 35 U.S.C. §112

Withdrawal of the prior rejection by the Examiner is hereby acknowledged and appreciated for claims 1-4, 6-18, and 20-33 under 35 U.S.C. 112, first paragraph. The clarifying amendment to these claims and prior explanation provided for the same remain notwithstanding anything stated to the contrary of record to date.

Claim Rejections under 35 U.S.C. §103:

Claims 1-4 and 6-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes (4725442) in view of Burke (5552156) and in further view of WO 99/61001.

Independent claims 1, 18 and 19 are amended herein to more clearly define the claimed embodiments of the invention over the cited references of record. In particular, Applicants direct the attention of the Examiner to a portion of the current specification that describes and distinguishes prior compositions including those described in Burke.

U.S. Pat. Nos. 5,552,156 and 5,736,156 describe liposomes and micelles of surfactant molecules for intravenous delivery of camptothecins. In liposomes, the camptothecin can reside bound to and partially in the membrane interlayer or dissociate into the internal enclosed aqueous layer in direct contact with water where the camptothecin lactone is not stable to hydrolysis. In micelles of surfactant molecules, the camptothecin is either in the central hydrocarbon portion of the micelle, bound to the micelle membrane or bound to the outside of the micelle. However, while camptothecins are less stable in micelles than in liposomes, especially in poly(ethylene oxide)-containing micelles, the amount of camptothecin compound that can bind to the membrane layer in a liposome is limited to the dimensions of the membrane and to the requirement that the membrane remain intact to prevent rupture of

the liposome. The ratio of lipid to camptothecin in liposomes is generally greater than 150, and the lactone of the camptothecin slowly hydrolyzes because of the reported equilibrium between bound and free camptothecin. [Specification, p. 3 (published application) US 20020150615, para. 11.]

The aforementioned distinctions and disadvantages of micelle structures in comparison to liposomes are largely ignored by Burke and other cited references. For example, Burke merely describes micelles as another structure for solubulizing camptothecin and without regard to membrane forming properties of selected lipids in relation to amounts or concentration of surface active agents in accordance with the invention. [Abstract; US 20020150615, para. 132-133 and 177.] The Examiner however is welcomed to cite any portions of such references to the Applicants that would suggest otherwise. Meanwhile, in the claimed embodiments of the invention herein, there is a clear intention to provide microdroplets with lipids that do not tend to form micelle structures and to better protect the enclosed camptothecin in the presence of surface active agents / surfactants. The membrane-forming lipids selected in accordance with the invention are chosen for their particular properties to achieve the desired results which are neither disclosed in or suggested by the references of record.

The Examiner is invited to contact counsel for the Applicants to address any questions or concerns. Given the status and history of this application, an Examiner Interview is believed to be warranted and would be most appreciated.

CONCLUSION

It is submitted that the present application is in form for allowance, and such action is respectfully requested. Should the Examiner have any questions, please contact the undersigned attorney.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 12636-898).

Respectfully submitted,

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